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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,534	11/20/2001	Charles V. Lowry	0410008	9912

23405 7590 04/17/2003

HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/17/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/989,534	Applicant(s) LOWRY, CHARLES V.	
	Examiner David A Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 17-18, 29, 33, 34, 38 and 39, drawn to a plasmid for use in monitoring the efficiency of a restriction digest, a method of designing the plasmid and kits containing the single plasmid, classified in class 435, subclass 320.1.
- II. Claims 12-16, 19-21, 22, 33, 35, 38 and 39, drawn to a set of two plasmids for use in monitoring the efficiency of a restriction digest, a method of designing the plasmids and kits containing the set of two plasmids, classified in class 435, subclass 320.1.
- III. Claims 12-16, 19-25, 33, 36, 38 and 39, drawn to a set of three plasmids for use in monitoring the efficiency of a restriction digest, a method of designing the plasmids and kits containing the set of three plasmids, classified in class 435, subclass 320.1.
- IV. Claims 12-16, 19-22, 26-28, 33, 37-39 and 40, drawn to a set of four plasmids for use in monitoring the efficiency of a restriction digest, in particular the set of plasmids indicated in Figure 1 of the specification of the instant application, and kits containing the set of four plasmids, classified in class 435, subclass 320.1.
- V. Claims 12-16, 19-22, 26-28, 33, 37-39 and 41, drawn to a set of four plasmids for use in monitoring the efficiency of a restriction digest, in particular the set of

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plasmids indicated in Figure 2 of the specification of the instant application, and kits containing the set of four plasmids, classified in class 435, subclass 320.1.

- VI. Claims 30-32, drawn to a method for monitoring the efficiency of a restriction digest, classified in class 435, subclass 6.

It is noted that claims 12, 19 and 20 are linking claims for groups II-V. If claims 12, 19 and 20 as originally recited, is present in an elected invention and found to be allowable, the non-elected inventions from groups II-V will be rejoined.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and effects and are not disclosed as capable of being used together. The inventions have different functions because each set of plasmids is designed to produce restriction fragments of different sizes in order to ascertain the efficiency of a restriction enzyme. By this design, the plasmids in each set must comprise a different nucleic acid sequence and structure to be recognized in such a manner to produce these fragments, therefore the plasmids must have different functions as a result of these different sequences and structures. This is particularly evident as it pertains to the specific plasmids shown in Figure 1 (group IV) and Figure 2 (group V), where different restriction sites (e.g., *SalI*) are used. In addition, the sets of plasmids are distinct from each other in that they have different effects, considering that a

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digestion of the different sets of plasmids results in a distinct set of restriction fragments.

Because the plasmids have distinct functions and effects, they represent patentably distinct inventions.

Inventions I-V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used for cloning purposes. Alternatively, the process of Group VI can be practiced with the patentably distinct inventions of Groups I-V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
March 21, 2003

Gerald B. Heffers
PATENT EXAMINER
Gerald B. Heffers Jr
A. 4. 1636